	INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 6/6/2019)	DATE: MRN: NAME:
APPROVED **26-MAR-2021** **INSTITUTIONAL REVIEW BOARD**	**PROJECT TITLE:** **Mindfulness-Augmented Cognitive Behavioral Therapy for Insomnia (MBTI) as a Step 3 Treatment for Non-remittent Insomniacs - A Pilot Study**	

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1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
Voluntary Consent. You are being asked to participate in a research study. Participation is voluntary. There will be no penalty or loss of benefits if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is to assess the effects of Mindfulness-Augmented Cognitive Behavioral Therapy for Insomnia (MBTI) on various measures of sleep and mood in people who still experience sleep disturbance following treatment with both digital and face-to-face Cognitive Behavioral Therapy for Insomnia (CBT-I). **Duration**. It is expected that your participation will last 8 months (8 weeks of therapy sessions and a 6-month follow-up). **Procedures and Activities**. You will be asked to meet with a nurse who has been trained in Mindfulness as it relates to insomnia for 1.5 hours each week for 1 intake session and 8 weeks of therapy. Meetings will be conducted one-on-one by video

conference. Participants will also be expected to maintain a personal meditation practice for the 8 weeks of the active therapy.

Risks. Some of the foreseeable risks or discomforts of your participation include possibly experiencing excessive sleepiness and/or distressing or anxiety-causing thoughts. Participants will be monitored for these potential events and referred appropriately as warranted. **If you are feeling sleepy, please do not drive or operate heavy machinery.** More detailed information can be found in the "*What Are The Risks, Discomforts, And Inconveniences Of The Study?*" section in the Consent Form. There may be additional risks and discomfort that are not known at this time.

Benefits. Some of the benefits that may be expected include improvements in your mood and your ability fall asleep and stay asleep throughout the night. You may also not be helped by this study. Still, others may be helped by what we learn from this study.

Alternatives. As an alternative to participation, you could talk with your doctor, get treatment in a clinical setting, participate in another research study, or choose to get no treatment.

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The Henry Ford Health System (HFHS) investigator(s) on this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Investigators may obtain salary or other financial support for conducting the research.

3. WHY IS THIS RESEARCH BEING DONE?

To make reading this consent form easier, the word "you" refers to you throughout the consent form.

You have been asked to take part in a research study because you have indicated through a follow-up questionnaire for a previous study (STRIDE: Study to Reduce Incident Depression Effectively; IRB 11586) that you are still experiencing difficulty falling asleep and/or staying asleep on a regular basis even after going through digital and face-to-face Cognitive Behavioral Therapy for Insomnia (CBT-I).

The purpose of this open-label research study is to evaluate a new treatment incorporating Mindfulness principles (such as letting be, awareness of thoughts, sensations, and emotions) into the more standardized practice of CBT-I to relieve insomnia in patients who haven't been helped by other methods.

A total of up to 40 people will be enrolled at Henry Ford Health System (HFHS).

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this study, your participation in this study will last a total of 8 months. As part of this study, you will have to complete an online baseline questionnaire, a single 1.5 hour screening/intake session with the therapist, 8 weekly 1.5-hour video visits, a short (<5 minute) weekly questionnaire to monitor your mood and well-being, a follow-up questionnaire at the completion of the intervention and then again at 6 months following the completion of the sessions.

The therapist will help you to use specific Mindfulness behavioral techniques to make adjustments in your sleep habits and how you think about your sleep, and to incorporate mindfulness principles into your daily routines to improve your ability to fall asleep and stay asleep throughout the night. Homework, in the form of meditations, is assigned each week and participants will keep a short meditation practice log and sleep diary. All study visits are conducted virtually.

The 8 weekly sessions cover education about sleep and sleep habits, meditation skills, how to manage thoughts, and problem-solving.

For some research studies, including the one you are being asked to join, you may be given the results of certain tests. For this study there are no test results to share.

This is an open-label study meaning that all participants will receive the same single intervention (MBTI).

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?

Category	Problem	Will be addressed
Side effects reported by patients, but not proven to be caused by treatment	Some sleepiness during treatment	• Will be monitored daily through sleep diaries during the study • Research staff available by phone or email (248-344-7362 or cfellma1@hfhs.org)
Side effects reported by patients	Increase emotional discomfort	• Will be monitored weekly through virtual sessions with the therapist • Research staff available by phone or email (248-344-7362 or cfellma1@hfhs.org) • Referral to a clinical behavioral health setting

The researchers will try to minimize risks through careful monitoring, review, and referral to clinical resources as appropriate. In the event research staff have reason to believe you are experiencing depression or suicidality, the sleep research team may place a referral to or communicate with your Primary Care Provider or Behavioral Health Specialist. If we cannot contact you within 24 hours of becoming aware of the change in your mental health status, a welfare check will be initiated.

If you are in crisis and need an emergency contact, please call 911 or go to the nearest emergency room. We **may** contact you to further assess any mental health needs. The phone number for the 24/7 national crisis management hotline is 1-800-422-1183.

If you are feeling sleepy, please do not drive or operate heavy machinery.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "How will my personal information be protected?"

A possible inconvenience may be the time it takes to complete the study.

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

There may be additional risks or discomforts that are not known at this time.

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include improved ability to fall asleep and/or stay asleep during the night, and improved personal well-being. You may not directly benefit from this research; however, we hope that others are helped in the future by what is learned.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

Participation is voluntary. Your other choices may include talking with your doctor, getting treatment in a clinical setting, participating in another research study, or getting no treatment.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or

specimens in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research information will not be made a part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Your identifiers will be destroyed upon completion of the final report.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without your additional informed consent.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. WHO DO I CONTACT WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Christopher Drake, or his staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report

an injury you may contact Dr. Christopher Drake by phone at 248-344-6672 or by email at cdrake1@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

You do not have to answer any question that you do not want to answer.

The employment and/or training of HFHS employees or residents who participate will not be affected if they decline to participate.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator (Dr. Christopher Drake), or your doctor can end your participation in the research study at any time. If this happens, you may be asked to meet with study staff for safety reasons.

13. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any cost to participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff.

14. WILL I BE PAID TO PARTICIPATE?

For taking part in this research study, you will be paid for your time and inconvenience. You will be paid $35 for each of three questionnaires, and $75 for each of 9 face-to-face video visits, one of which is a screening/intake. You will be paid at completion of each stage (end of first questionnaire, end of the last therapy session, and after completing the second and third questionnaires). If you complete the study, you will be paid a total of $780. If you do not finish the study, you will be paid for the part that you did complete.

You will receive payment via a ClinCard, which is a specially designed debit card for clinical research that works like a bank debit card. Each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. The debit card system is administered by an outside company. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. In order to receive payment, we will need to collect some information about you, including your name, address, date of birth, ~~medical record number,~~ and social security number. All information is stored in a secure fashion and will be deleted from our records once the study has been completed and the funds on your ClinCard have been exhausted.

You may use this card at any store that accepts credit cards. You may also withdraw cash. Please be aware that there may be fees drawn against the balance of the card for cash withdrawals and

inactivity. You will receive additional information on how you can use this card and any fees that may apply.

IF PAYMENTS COULD EXCEED $600: HFHS is required to report payments of $600 or more to the Internal Revenue Service (IRS). If you receive $600 or more from participating in research at HFHS during the calendar year, your compensation will be reported to the IRS and you will also receive an IRS 1099 Form.

DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I am willing to be contacted for future research studies. Please initial below.

_____ I agree

_____ I refuse

I understand that this study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still participate in this study. Please initial below.

_____ I agree to be video/audio recorded/photographed.

_____ I refuse to be video/audio recorded/photographed.

_____	_____	_____
Signature of Subject	Date	Time

_____

Printed Name of Subject

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

_____

Printed Name of Person Obtaining Consent